



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/319,521 06/04/99 PITTENGER

M 640100-326

HM22/0117

RAINA SEMIONOW
CARELLA BYRNE BAIN GILFILLAN CECCHI
6 BECKER FARM ROAD
ROSELAND NJ 07068

EXAMINER

TUNG, M

ART UNIT

PAPER NUMBER

1644

7

DATE MAILED:

01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/319,521

Applicant(s)
Pittinger, et al.

Examiner
Mary B. Tung

Group Art Unit
1644

☒ Responsive to communication(s) filed on Oct 27, 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-3, 5-16, 18-27, and 29-41 is/are pending in the application

Of the above, claim(s) 1-3, 5-13, 36, and 39 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 14-16, 18-27, 29-35, 37, 38, 40, and 41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse, of Group II, claims 14-16, 18-27, 29-35, 37, 38, 40 and 41, drawn to a process of producing chondrocytes in the paper filed October 27, 2001, Paper No. 6 is acknowledged. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Group I, claims 1-3, 5-13, 36, and 39, drawn to a composition comprising mesenchymal stem cells are withdrawn from further consideration by the Examiner, 37 C.F.R. 1.142(b), as being drawn to non-elected inventions.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 U.S.C. § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 22, 33, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "high-glucose" in claims 22 and 33 is a relative term which renders the claim indefinite. The term "high-glucose" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 14, 15, 18, 19, 20, 23, 25, 26, 29, 30 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Itay, et al. (US Patent No. 5,053,050).
9. Itay, et al. (US Patent No. 5,053,050) teach a method for producing chondrocytes from mesenchymal stem cells comprising contacting mesenchymal stem cells with growth agents and wherein the mesenchymal stem cells in a three dimensional format (see the abstract, col. 2, lines 50-54 and col. 3, lines 8-39). The growth agents listed in col. 3, lines 20-22 are interpreted as chondroinductive, as recited in claim 1, since the resulting cells display a chondrocyte phenotype (see col. 3, lines 32-34). The step wherein the mesenchymal stem cells are isolated and culture expanded, as recited in claim 15, is taught in col. 4, lines 31-43. The step of the cells being human would be encompassed by the reference teaching in that the bone marrow containing the mesenchymal stem cells was obtained from mammalian species and the method steps would be the same. The step wherein the chondroinductive agent is TGF- β is taught in col. 3, lines 20-23. The step wherein the cells are present as packed cells or a centrifugal cell pellet is taught in col. 4, lines 37-44. Therefore, the '050 patent anticipates the invention.
10. Claims 14, 15, 18-20, 23-26, 29-31, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bruder, et al. (US Patent No. 5,736,396).
11. The '396 patent teach a method for producing chondrocytes from mesenchymal stem cells comprising contacting mesenchymal stem cells with growth agents and wherein the mesenchymal stem cells are in a three dimensional format (see the abstract, col. 7, lines 44-47) in porous calcium phosphate ceramics. Chondroinductive agents, including TGF- β 1 and dexamethasone are taught in col. 8, lines 11-25. The step wherein the mesenchymal stem cells are isolated and culture expanded, is taught in col. 7, lines 44-50. The step of the cells being human would be encompassed by the reference teaching in that the bone marrow containing the mesenchymal stem cells was obtained from mammalian species and the method steps would be the same. The recitation wherein the cells are placed in a ceramic cube is not considered to be a critical step, since the Applicants have not provided guidance as to why the shape of the ceramic is a critical step in the method, and other shapes, such as spheres or space-specific molded shapes would also be equivalent shapes. Therefore, the '050 patent anticipates the invention.

Claim Rejections - 35 U.S.C. § 103

12. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 14-16, 18-27, 29-35, 37, 38, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruder, et al. (US Patent No. 5,736,396) in view of Hunziker (US Patent No. 5,368,858).

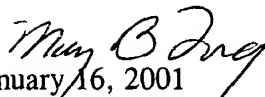
14. The '396 patent has been discussed, *supra*. The claimed invention differs from the reference teaching only by the recitation of the use of a medium free of serum, as recited in claims 16, 21 and 32. The '396 patent does not teach a high glucose medium serum free medium, nor the use of TGF β 3, as recited in claims 37 and 38. The '858 patent teaches the use of TGF- β 3 in a method of proliferating chondrocytes and states that the activity among members of the TGF- β family are similar (see col. 8, lines 7-24). It is well known in the art that high glucose medium decreases cultured endothelial cell proliferation and one of ordinary skill in the art would recognize that in order to culture bone marrow derived mesenchymal stem cells, it would be desirable to limit the growth of the non-target endothelial cells which would be present in the primary bone marrow aspirate. Additionally, one of ordinary skill in the art would recognize that the recited concentrations in claims 40 and 41 are well within recognized concentrations of high glucose mediums. One of ordinary skill in the art at the time the invention was made would have been motivated to use serum free medium in the method of the '396 patent, in order to more clearly define the components of the medium, to lower costs, and to lower a possible immune response against foreign species proteins found in the regularly-used fetal bovine or horse serums and to include high glucose concentrations in the medium in order to limit the proliferation of endothelial cells. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

15. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published

in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.


January 16, 2001
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

MARY BETH TUNG, PH.D.
PATENT EXAMINER